TCE: Health-Based Criteria and Air Guideline

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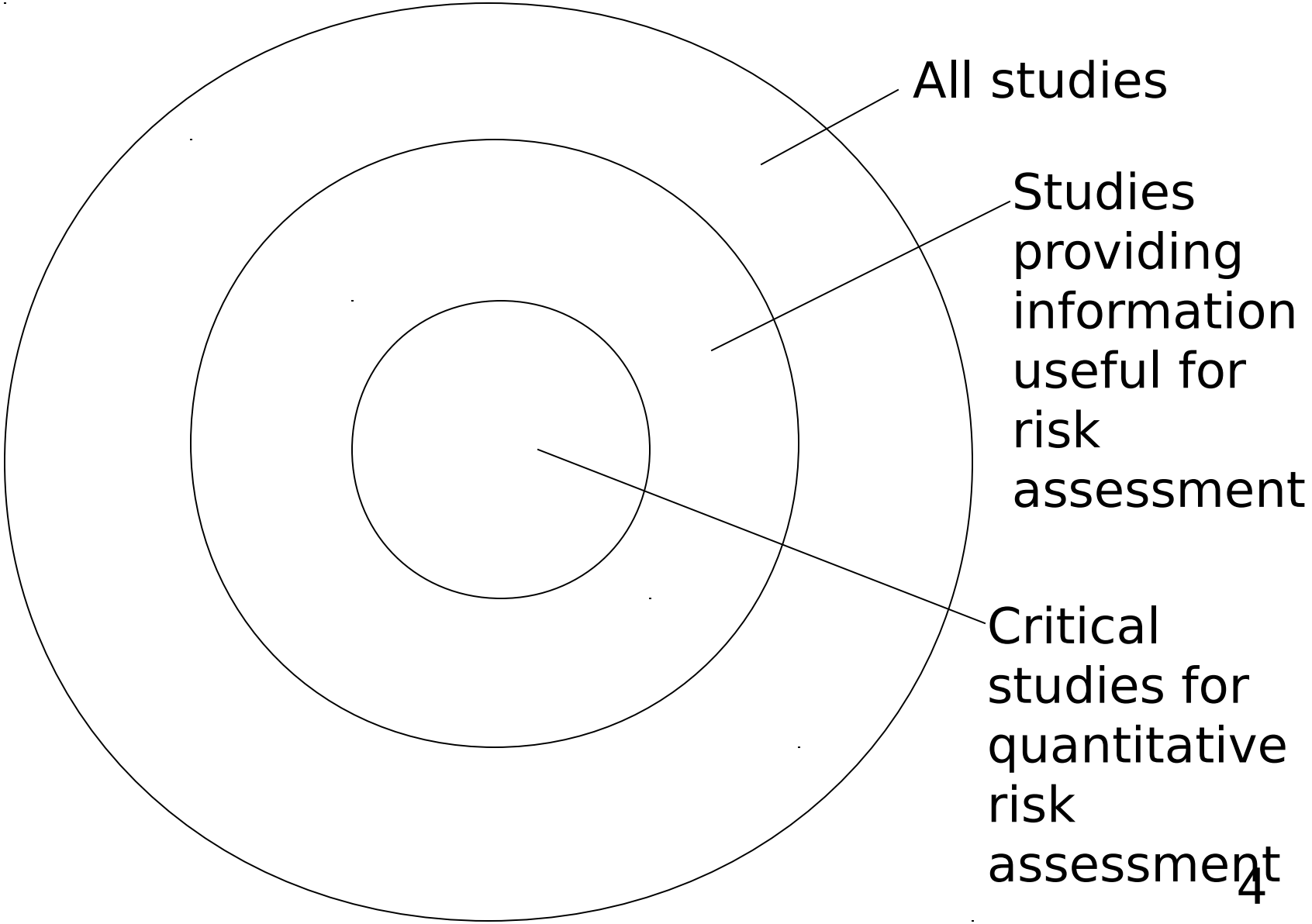
NYS DOH TCE Guideline

- Take action above
- Reduce to background as practical
- Voluntary risks
- Involuntary risks (e.g., SVI)

NYS DOH Trichloroethene Air Criteria Document

- Draft Competed August 2005
- Expert Panel Review August 2005
- Final October 2006

TCE Toxicity Studies


All studies
Studies providing information useful for risk assessment
Critical studies for quantitative risk assessment

Health-Based Criteria

- Potential criteria
  - Critical and supporting studies
  - Plausible assumptions about active agent/mode of action and low dose extrapolation
  - Different lifestages
- Recommended criteria
  - Critical studies
  - Further evaluation of active agent/mode of action and low dose extrapolation
  - Different lifestages
- Selection of criteria for each endpoint

Non-Carcinogenic Effects: Criteria Used in Guideline Derivation

Organ/System/ Lifestage	Study*	Recommended TCE Criteria (mcg/m^3)	
		Study	**System**
CNS	Arito et al. (1994)	4 (childhood)	10
	Rasmussen et al. (1993)	11 (adult & childhood)	
Liver	Kjellstrand et al. (1983)	160 (adult & childhood)	160
Kidney	Kjellstrand et al. (1983)	160 (adult & childhood)	160
Reproduction	Land et al. (1981)	32	20
	DuTeaux et al. (2004)	110	
	Kumar et al. (2000; 2001)	20	
	NTP (1986)	110	
Developmental	Dawson et al. (1993)	11 (supporting study	20
	Healy et al. (1982)	38	
	Isaacson & Taylor (1989)	19	
	NTP (1986)	22	

*References provided in Final Report Trichloroethene Air Criteria Document (2006).

Carcinogenic Effects: Criteria Used in Guideline Derivation

Cancer	Recommended Air Criteria (mcg/m^3) (Excess Lifetime Cancer Risk of 1 x 10^{-6})*			
	LADE		LADD (PBPK)	
	Unadjusted	Adjusted**	Unadjusted	Adjusted**
Animal Data (Fukuda et al., 1983; Henschler et al., 1980; Maltoni et al., 1986)***				
liver	1.8	1.1	1.4	not done given limits on PBPK models for children
kidney	13	7.8	3100	
lymphoma	0.3	not done given uncertainty in mode of action	not done given uncertainty in appropriate internal dose & mode of action	
testes tumors	not a recommended site			
lung	not a recommended site			
Human Data (Hansen et al. (2001)***				
esophagus	0.36 – 1.2	not done given uncertainty in mode of action & appropriate internal dose		
NHL	0.29 – 0.91			

* 1 x 10^{-6} values given from comparative purposes.

** Adjusted for the potential increased sensitivity of children to early-life TCE exposures.

***References provided in Final Report Trichloroethene Air Criteria Document (2006).

Carcinogenic Effects: Summary Table of Criteria Used in Guideline Derivation

Basis	Recommended Criteria (mcg/m^3)				Human
	Animal				
	Kidney		Liver	Lymphoma	NHL/ Esophagus
	LADE	PBPK	PBPK	LADE	LADE
Excess Risks (linear extrapolation)					
1 x 10^{-6}	7.8*	3100	1.4	0.3	0.4
1 x 10^{-5}	78*	31,000	14	3	4
1 x 10^{-4}	780*	310,000	140	30	40
RfC (non-linear extrapolation)	430	100,000	48	none	none

* Calculated using age-dependent adjustment factors applied to unit risk estimate to compensate for potential increased sensitivity of children (US EPA, 2005).

Guideline Derivation

- Health Risks
- Analytical Methods
- Background Air Concentrations

Health Risks

- Non-Carcinogenic Effects
  - Can't exceed recommended criteria for organ/system/lifestage (i.e., 10 mcg/m^3)
- Carcinogenic Effects
  - Can't exceed 1 x 10^{-4} excess cancer risk (i.e., 30 mcg/m^3); approach 1 x 10^{-6} (i.e., 0.3 mcg/m^3) as practical

Maximum TCE Guideline

- Guideline could be 10 mcg/m^3
  - It is equal or lower than all recommended criteria based on non-carcinogenic effects
  - Estimated lifetime excess cancer risks within range generally used in regulatory programs

Analytical Methods

- Samples should be analyzed by methods that can achieve minimum reporting limits to allow for assessments such as comparison to background levels and an evaluation of health risks.

- Methods should be routine and cost-effective.

Background Considerations

- Guideline should not be below background concentrations.

- TCE Background Data (mcg/m^3)

Reference	Percentile			
	50th	75th	95th	99th
NYS DOH	<0.25	<0.25	0.5	1
US EPA	<1.4	1.2	4.2	6.5
Weisel et al.	0.12		1.36	

TCE-Specific Considerations

Health Risks

- Data gaps
  - Congenital heart defects
  - Immunotoxicity

- Risk assessment methods of childhood exposures

- Cancer risks estimates given increased weight since evidence has increased that TCE is a human carcinogen

Other TCE-Specific Considerations

- Analytical Methods
  - 0.25 mcg/m^3 - 1 mcg/m^3
- Background Air Concentrations
  - Mostly less than 1 mcg/m^3 but upper percentiles can be up to about 5 mcg/m^3

Criterion to Guideline

Additional Factor of 2 Applied to 10 mcg/m^3

- Increases margins-of-exposure for non-carcinogenic effects
- Decreases cancer risks
- Can be detected reliably
- Closer to background levels

Summary - Derivation of Guideline

- Health-Based Criteria
  - Non-Carcinogenic Effects
  - Carcinogenic Effects
- Data Gaps and Cancer Risk at Guideline

- Other Considerations
  - Analytical Methods
  - Background Concentrations

Guideline of 5 mcg/m^3